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IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA, *Et Al.*,
Appellants,

v.

AUTOMATED MEDICAL LABORATORIES, INC.,
Appellee.

On Appeal From the United States Court of Appeals for the Eleventh Circuit

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BRIEF OF AMERICAN BLOOD RESOURCES ASSOCIATION AND FLORIDA ASSOCIATION OF PLASMAPHERESIS ESTABLISHMENTS AS *AMICI CURIAE* IN SUPPORT OF APPELLEE

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QUESTION PRESENTED

Does a comprehensive scheme of Federal regulation of plasmapheresis, designed to promote a national policy for uniformity in blood banking and plasmapheresis, and to assure both donor safety and product quality, preempt Hillsborough County, Florida regulations that conflict with the Federal regulations yet do not achieve any legitimate purpose not already covered in the Federal Regulations?

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BRIEF OF AMERICAN BLOOD RESOURCES ASSOCIATION (ABRA) AND FLORIDA ASSOCIATION OF PLASMAPHERESIS ESTABLISHMENTS (FAPE) AS *AMICI CURIAE* IN SUPPORT OF APPELLEE

INTEREST OF *AMICI CURIAE*

ABRA is a not-for-profit trade association. Its approximately eighty members* operate about three hundred plasma collection facilities, manufacture plasma-based pharmaceuticals, chemistry controls and blood banking reagents, and engage in research and development of new products. ABRA's members, whose facilities are located in about 212 communities in 42 states, produce and distribute about 70% of the plasma products used in the United States.[1]

* A list, pursuant to rule 28.1, of corporations which are (1) members of American Blood Resources Association (ABRA), or Florida Association of Plasmapheresis Establishments (FAPE), *Amici Curiae* herein, (2) parents or affiliates of members of ABRA or FAPE, or (3) not included in categories (1) or (2) but which may have an interest in this case has been lodged with the Clerk of this Court. The list is believed to include all corporations now known by ABRA to be engaged, directly or indirectly, in plasmapheresis or the manufacture and distribution of plasma products.

[1] There are approximately 350 plasma collection centers in the United

ABRA's members include sole proprietorships as well as large multinational corporations.[2] FAPE, with 11 members operating 20 plasma centers in Florida, is affiliated with ABRA.[3] It represents Florida plasmapheresis centers regarding state legislative issues as well as local concerns, such as arise out of the Ordinances challenged in this case.

Plasma, the clear fluid portion of the blood, contains a variety of protein substances essential for manufacture into products used extensively in the health care industry.[4] "Injectables," or products made from plasma for human use, include volume expanders, antihemophilic factor (AHF), and such immune products as Rh immune globulin and hepatitis vaccine.[5] ABRA's members furnish about 80% of

States. Industry estimates that it recruits and collects plasma from some 46,000 donors, by plasmapheresis, each day, representing an annual total of 10 million plasmapheresis collections. Those collections will meet about 60 percent of the world's raw plasma requirements. In 1983, the commercial plasma industry produced an estimated 6 million liters of source plasma, 4.7 million liters for fractionation into pharmaceuticals and manufacture of diagnostic products, and 1.3 million liters for export.

[2] ABRA seeks to develop a sound regulatory framework designed to promote donor safety and product safety and efficacy, encouragement of better understanding of the proprietary plasma industry, and adherence by its members to a code of ethical practice. ABRA's Code of Ethics is included as Appendix A hereto. ABRA's objectives are achieved through a variety of activities, including publication of *Plasma Quarterly*, a scientific and management journal; sponsorship of an annual "Plasma Forum" which attracts the world's leading authorities on scientific and technological aspects of plasmapheresis; and liaison with FDA officials and Congress regarding plasma regulatory issues.

[3] Appellee Automated Medical Laboratories, Inc., is a member of ABRA and FAPE.

[4] Source Plasma (Human) is a product defined as plasma obtained by plasmapheresis. 21 C.F.R. § 640.60. In the plasmapheresis procedure, blood is removed from a human donor, the plasma and red blood cells are separated, and the red cells are returned to the donor.

[5] Hepatitis vaccine, a relatively new product, is manufactured using plasma which contains hepatitis antigen. Hepatitis vaccine may reduce the incidence of Hepatitis B, a major health problem. Rh immune globulin is

the AHF used by this country's approximately 20,000 hemophiliacs. Since AHF became available in the late 1960s, it has greatly improved the quality of life and life expectancy of hemophiliacs since it allows home care treatment and substantially reduces the amount of hospitalization and health care services needed by hemophiliacs. *See*, generally, Aledort, "The Availability of Plasma Products and the Care of Hemophilia Patients," 246 *J.A.M.A.* 157 (July 10, 1981); Massie and Massie, *Journey* (Knopf, 1976) (the account of raising a hemophiliac son); Child, "Hemophiliacs and Plasma," *Plasma Forum* 25 (McNally & Loftin, West 1979). Plasma is also manufactured into important "non-injectable" products such as blood grouping and typing sera and other laboratory and diagnostic reagents.[6]

ABRA, FAPE and their members have a strong interest in the outcome of this case because it may adversely affect necessary uniformity in the application of regulations and the adequacy of the supply of plasma and plasma products. Although the Federal government determined what regulatory measures were necessary to promote both donor safety and product quality and at the same time assure that there

manufactured using plasma containing Rh-antibody. Each year approximately 320,000 women will deliver Rh positive infants. In the past, those deliveries would have resulted in a 10 percent incidence of potential brain damage or death to the newborn. Since the introduction of Rh immune globulin in the late '60s, more than 2,000 deaths and thousands more injuries have been prevented. Probably the most widely used plasma products are protein replacement fluids used extensively as volume expanders for burn patients, in surgery, and in treatment of trauma.

[6] Blood grouping and typing sera are used in blood banking to assure proper blood grouping and typing. In the past year, there were over 14 million blood components prepared and over 3 million patient transfusions. Those activities could not have occurred safely without high quality plasma products. Every hospital patient benefits from plasma based reagents and diagnostics. For example, a standard admissions routine, the complete blood count, requires plasma based control reagents. Some reagents can be made from plasma from only one or a handful of individuals in the country who possess the rare antibodies needed. Reagents and typing sera rely on commercial plasma collection almost exclusively.

is an adequate source of plasma for products used in the health care industry, Hillsborough County has determined that FDA's donor safety measures were inadequate and adopted the Ordinances. These *Amici* believe that the County's regulations will produce shortages of products like AHF and Rh immune globulin, significantly impacting the hemophiliac community and the health of newborn babies. The entire health care community will be affected. The County, like any other local jurisdiction, is not concerned about the implications of its regulatory actions on the availability or price of plasma and plasma products and thus produced an independent regulatory scheme in conflict with the Federal regulations.

STATEMENT OF THE CASE

A. *Plasmapheresis, Donors and Centers.* Because plasmapheresis takes much longer than whole blood donations, the commercial industry evolved and pays donors for their time. Plasmapheresis may safely be done twice a week because the red blood cells are returned to the donor. 21 C.F.R. § 640.65.[7] Intensive plasmapheresis, regulated under Federal law, is recognized to be safe for the donor.[8]

[7] Generally, a person involved in a regular plasmapheresis program donates plasma between 40 and 60 times per year.

[8] See *e.g.*, Office of Technology Assessment, U.S. Congress "Blood Policy and Technology," Report H-260 (OTA), at 40-41 (1985); FDA Panel on Review of Blood and Blood Derivatives, "Human Plasma as a Source for Fractionation Products," (Draft Report, Nov. 15, 1979); Dawson, *et al.*, "Protein and Hematocrit Value in Long-Term Plasmapheresis Donors," 1 *Plasma Quarterly* 13 (February 1979); Salvaggio, "The Effect of Prolonged Plasmapheresis in Immunoglobulins, Other Serum Proteins, Delayed Hypersensitivity and Phytohemagglutinin, Induced Lymphocyte Transformation," 1 *Plasma Quarterly* 44 (June 1979); Ascari, "Effects on Protein Components during Plasmapheresis for Six Months to Six Years," *Plasma Forum* 119 (ARBA 1980); Cohen, et al., "Hemotologic and Biochemical Observations During Health Surveillance of Plasmapheresis Donors," *Plasma Forum III* 201 (ABRA 1981); Dawson *et al.*, "Laboratory Findings on Long Term Plasmapheresis Donors: Protein Levels," *Plasma Forum III* 209 (ARBA 1981).

Although the stereotype plasma donor is a skid-row alcoholic or narcotics addict, this is far from accurate: blue collar workers, housewives, and university students are the principal donors.[9]

B. *FDA's Plasmapheresis Regulations.* FDA regulates plasmapheresis and blood banking pursuant to comprehensive regulations promulgated under Section 351 of the Public Health Service Act ("PHS Act"), 42 U.S.C. § 262 (1982), and the drug provisions of the Federal Food, Drug and Cosmetic Act ("FDC Act"), 21 U.S.C. §§ 301 *et seq.*[10] These regulations carefully balance the need for donor safety and product quality against the need to assure an adequate supply of plasma. In addition to provisions on donor eligibility, the regulations contain provisions relating to, among other things, establishment and product

[9] Rodell, "Profile of 6000 New Plasmapheresis Donors," 5 *Plasma Quarterly* 42, 57 (Spring 1983). This study of data on over 14,000 donors at more than 20 locations in a dozen states revealed that 77% are white, nearly 70% are under the age of 30, 86% are under 40. Eighty percent of the donors are male. Almost 32% are college students. Most of the balance are blue collar workers or house wives. In another study, industry members characterized the locations of their centers. Most plasma centers—about 60%—are in professional, college or university areas. Residential and industrial areas account for a small percentage, 15%. Fahle, "The Source Plasma Industry: Statistical Report, 1979," 3 *Plasma Quarterly* 68, 69 (Sept. 1981).

[10] Approximately 110 pages of regulations apply to blood and blood products. These reflect in elaborate detail, the requirements of PHS Act Section 351. The present Source Plasma (Human) regulations originated in a 1972 proposal. FDA worked with a panel of experts to craft requirements designed to achieve twin goals of (1) product safety and efficacy and (2) donor safety. Donor safety was emphasized from the very beginning:

> To insure there is a ***continued healthy donor population to serve as a source of plasma*** to be used in the manufacture, by the fractionation technique, of safe, pure, and potent and blood products, the Commissioner is including in these proposed additional standards for Source Plasma (Human) ***specific provisions designed to protect the health and well-being of the donor.***

37 *Fed. Reg.* 17,420 (1972) (emphasis added).

licenses, annual or periodic inspections, good manufacturing practices, storage, labelling, records, reports, and standards for derivatives and reagents. 21 C.F.R., Parts 600, 601, 606, 607, 610, 640, 660 and 680. These regulations operate as an integrated whole and cannot be segmented. FDA also frequently issues guidelines and reviews plasma center operating procedures as part of its regulatory program. Plasma industry activities are regulated, in effect, from "soup to nuts."

Of most relevance here are the regulations expressly relating to donor health and safety. Donor suitability is carefully delineated. 21 C.F.R. § 640.63. A potential plasma donor must undergo a well-defined medical examination performed by a physician employed by the plasmapheresis facility and show satisfactory results for such tests as urinalysis, syphilis, total plasma protein, and specific protein composition. At the initial and each subsequent donation, donor center staff must ask questions regarding donor health, follow specific procedures relating to Acquired Immune Deficiency Syndrome (AIDS), and perform tests, including temperature, blood pressure, pulse, total protein and hematocrit. As a result of these tests, a donor's suitability—including the possibility of overbleeding—is evaluated. A donor's initial exam and processing generally takes three to four hours. Each unit is subsequently tested for hepatitis antigen. 21 C.F.R. § 640.67. Routine testing for the antibody to the causative agents of AIDS is now being implemented. Every four months the protein composition test and syphilis test are repeated, and the physician must review laboratory data and the donor records. 21 C.F.R. § 640.65. Annually, the urinalysis and physician's examination must be repeated. 21 C.F.R. § 640.63(b).

C. *Hillsborough County Regulations.* In 1980, Hillsborough County, Florida ("County") promulgated two ordinances relating to plasmapheresis, and the County Department of Health ("Department") issued regulations thereunder. Ordinance 80-11 imposes a license tax, a public hearing process, requires the center to give "reasonable

and continuing access" to Department personnel for inspections, and to provide current information regarding personnel, equipment and facilities. (J.A. 21-23)

Ordinance 80-12 deals with donor registration. Its purpose is to provide a system for

> . . . registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interests of the health of the people of Hillsborough County. (J.A. 24-25)

Ordinance 80-12 applies only to "commercial blood plasma vendors"—people who sell, barter or exchange their plasma (through plasmapheresis) for a monetary consideration. Ordinance 80-12 incorporates by reference the provisions of the Federal regulations relating *solely* to Source Plasma (Human), 21 C.F.R. Part 640, subpart G, §§ 640.60 *et seq.*, "as they may be amended from time to time." The key provisions of the County Scheme include:

—A donor registration requirement whereby a person is eligible to donate only after (i) being examined by a physician and obtaining a certificate of good health, (ii) obtaining (for $2.00 paid to the County) a registration card valid only for six months solely at one designated plasma facility, (iii) being free of hepatitis, as shown by test, and (iv) swearing an affidavit that he has not been "detained" or "treated" for acute or chronic alcoholism during the preceding 12 months. (J.A. 32)

—A fee of $1.00 for each plasmapheresis collection to be paid by the center to the County. (J.A. 27)

—A requirement that a donor take an alcohol breath-analysis prior to each collection of plasma. (J.A. 28)

—Annual inspection of the plasma center by the County. (J.A. 28)

—Delivery every day by the center to the County of detailed information about each plasmapheresis collection. (J.A. 29)

Ordinance 80-12 subjects plasma centers to criminal sanctions for violation of its provisions. (J.A. 31)

The County Scheme's requirements do not relieve the plasma center from complying with Federal regulations.[11] For example, while a County resident must have had a physical exam to obtain a donor registration card, a person possessing the requisite registration card must nevertheless be thoroughly examined by the plasma center physician pursuant to Federal regulations. And, although Federal regulations permit plasmapheresis of any healthy person, whether from the County or elsewhere, a center in the County cannot plasmapherese such a person unless he possesses a donor ID. Even if a registered donor is pretested for hepatitis under the County scheme, each unit of plasma must be tested and be "non-reactive" to hepatitis B-surface antigen under the Federal scheme. 21 C.F.R. § 640.67. Likewise, all the Federal donor suitability requirements for each donation must be complied with even though the donor has a County donor registration card.

D. *The Decision Below.* In a unanimous decision written by Chief Judge Tuttle, the Eleventh Circuit held that FDA's blood plasma regulations preempted all provisions of the County's scheme under the principles enunciated in *Pennsylvania* v. *Nelson*, 350 U.S. 497, 502-510 (1955). J.A. 48-59. The Court of Appeals found that the "pervasiveness" of the "comprehensive" federal regulatory scheme "makes it reasonable to infer that Congress left no room for local ordinances to supplement it." J.A. 55-57. Based on agency regulations reflecting a uniform National Blood Policy emphasizing an adequate, safe supply of blood and blood products, the court concluded that the field of plasma-

[11] Section 351's mandate is unlike the Clinical Laboratories Improvement Act of 1967, 21 U.S.C. § 263a, which permits exemption from federal licensing and inspection where the laboratory meets local requirements equal to or more stringent than the federal standards and which explicitly saves to the States the power to act "to the extent that such laws are not inconsistent with" the Federal act. 21 U.S.C. § 263a(k).

pheresis was one in which the federal interest was dominant over any state or local interest. J.A. 57-58. Finally, the court ruled that the requirements imposed by the County's ordinances were "burdensome and expensive" and would frustrate "the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors." J.A. 58-59.

SUMMARY OF ARGUMENT

Whether federal law preempts local laws is a question of law to be determined by this Court. The Federal agency's view, therefore, is not dispositive but may be given weight and deference. Here, FDA's 1973 comment that its regulations were not intended to "usurp" local regulation of plasmapheresis related to a limited regulatory scheme. The regulations were subsequently broadened into a comprehensive, complete regulation of plasmapheresis, consistent with the National Blood Policy. The regulatory program itself evidences a stringent, thorough, complete approach to its subject matter. Thus, the Commissioner's 1973 statement cannot be dispositive of the question presented.

The Eleventh Circuit correctly applied the three tests of *Pennsylvania* v. *Nelson*, 350 U.S. 497 (1955).

(1) The comprehensiveness of the regulations is conceded by the United States. (U.S. Br. p. 7.) In any case, it is evident from an examination of the regulations themselves and the voluminous interpretive guidelines published by FDA. The County's regulations duplicate FDA's scheme and differ only in the methods selected to deal with specific aspects of plasmapheresis. Thus, the County scheme provides no protections not afforded by FDA's regulations and no real "local" interests, such as federalism traditionally recognizes, are served.

(2) The National Blood Policy declared the interest of the United States in a safe and adequate blood supply and

required that the full regulatory authority of the United States be applied to the practices of blood banking, including plasmapheresis. Progress toward achievement of the National Blood Policy has been scrutinized by Congress and its agencies. In any case the need for blood plasma and plasma products in the health care system establishes the national interest in the safety and efficacy of blood and blood products.

(3) The County scheme conflicts with the Federal regulations, particularly in the all important issue of donor suitability. The County scheme proceeds from a philosophical base different from that of FDA's regulations. FDA's regulations are premised on the twin concerns of product safety and efficacy *and* donor safety. In adopting the plasma regulations, the Commissioner took every reasonable step to assure donor safety and, at the same time, recognized his correlative duty to ensure that plasma donor suitability standards would not constitute a barrier to assuring an adequate source of supply for these vital products. 37 *Fed. Reg.* 17,420 (1972). By contrast, the County, purportedly exercising its police powers to protect the health of its residents, has adopted regulations that are concerned solely with donor safety, thus ignoring the national need to assure an adequate source of supply. This factor is the very heart of the conflict between the Federal regulations and the County scheme: FDA's regulations permit each and every healthy individual who meets specified criteria to donate plasma freely and of his or her own choice, while the County scheme allows an otherwise eligible donor to donate only if the County approves his doing so. FDA—and not the County—is competent to balance the needs of donor safety with the need to assure an adequate supply of plasma products. The County's burdensome and expensive requirements will frustrate the National Blood Policy's goals of uniformity in blood banking and plasmapheresis practices and will affect the adequacy of plasma supplies.

ARGUMENT

SINCE FDA'S COMPREHENSIVE PLASMA REGULATIONS IMPLEMENT A NATIONAL POLICY FAVORING UNIFORMITY AND ASSURING AN ADEQUATE PLASMA SUPPLY, THEY MUST PREEMPT LOCAL REGULATION WHICH CONFLICTS WITH OR FRUSTRATES THAT NATIONAL POLICY

A. "Preemption or No" is a Question of Law to Which FDA's 1973 Comment is Not Germane

This Court has held that whether federal law preempts a body of local law is a question of law. *Pacific Gas and Electric Co.* v. *State Energy Resources Conservation and Development Commission et al.*, 461 U.S. 190, 202 (1983). Accordingly, the Commissioner's 1973 statement that the regulations "are not intended to usurp" local authority to regulate plasmapheresisis, 38 *Fed. Reg.* 19,365 (1973), would normally be entitled to deference, but it is not dispositive of the question in this case.

Considered in isolation, this preamble statement might be evidence of the agency's views. Within months, however, the Commissioner was referring to "uniform high quality throughout the nation," "uniform and efficient enforcement of the law," 39 *Fed. Reg.* 18,615 (1974), "strict regulatory controls" and "comprehensive donor protection requirements," 39 *Fed. Reg.* 26,161 (1974), and later yet to "more stringent requirements than originally proposed," 41 *Fed. Reg.* 10,762 (1976). This change is not surprising, as the 1973 proposal was aimed only at procedures producing plasma for injectable products. 38 *Fed. Reg.* 19,362 (1973). Only a few months later, FDA realized that the goal of donor protection required that the regulations extend to all plasmapheresis procedures. 39 *Fed. Reg.* 26,161 (1974).

Moreover, after the Commissioner's 1973 comment, the Department of Health, Education and Welfare,[12] of which FDA is a part, participated in the development of the

[12] Now the Department of Health and Human Services. 20 U.S.C. § 3508.

National Blood Policy. That Policy articulated the goals of assuring an adequate supply of safe blood and blood products and employing "the *full regulatory authorities now vested* in the Federal Government . . . for the purpose of *assuring uniform adherence to the highest attainable standards* of practice in blood banking, *including plasmapheresis and plasma fractionation.*"[13] 39 *Fed. Reg.* 32,703 (1974) (emphasis added). Thus, it is not surprising that in 1973 the Commissioner might hesitate to "usurp" local authorities yet by 1974 be writing "comprehensive" and "stringent" regulations to result in products "of uniform high quality throughout the nation." The Commissioner also noted that, "The Supreme Court has reaffirmed that it is 'implicit in the regulatory scheme' for [FDA] to pursue a comprehensive, industry-wide program for a particular class of drugs 'for the achievement of the agency's ultimate purposes,' " citing *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 655 (1973). 39 *Fed. Reg.* 18,615 (1974).[14]

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[13] Hillsborough County and the Solicitor General argue incorrectly that the National Blood Policy excluded the commercial plasmapheresis industry (County Br. p. 8; U.S. Br. p. 22). The National Blood Policy established the goal of an all volunteer supply for blood and blood products. But the National Blood Policy recognized that achieving this goal for acquisition of plasma was not practical "for the time being" because the volunteer community could not meet the demand for plasma. Accordingly the National Blood Policy excepted plasma from its all volunteer goal but in all other respects the National Blood Policy extended its requirements and goals—including that of "uniform adherence to the highest attainable standards"—to plasmapheresis. Similarly the argument that the National Blood Policy envisioned cooperative regulation by the states (County Br. pp. 8-9) misses the point. Any references to a possible role for state health departments are solely in the context of discussing regionalization of blood banking and transfusion services, 39 *Fed. Reg.* 32,707, 32,708 (1974), not plasmapheresis.

[14] Ironically, the very language cited by the County to show that the Commissioner recognized a dual system of regulation (" 'The Commissioner finds these programs are inadequate.' " County Br. p. 9 n.8) is how a federal agency would justify preempting local regulation, namely its inadequacy to accomplish the Federal goals, and was written after the March 1974 announcement of the National Blood Policy. 39 *Fed. Reg.* 18,614-15 (1974).

Nor is the Commissioner's 1973 pronouncement consistent with the FDA's regulatory approach, particularly since 1976. FDA has not regarded its authority as being limited to the formal promulgation of regulations and the inspection and licensing of facilities. Recognizing that medical knowledge is evolutionary, FDA publishes guidelines and interpretations on an as-needed basis. Over the years, the volume of these guidelines has been substantial. While these guidelines do not have the status of law, they are binding upon the agency in the sense that a person who acts in accordance with them is regarded as complying with Federal law. *See* 40 *Fed. Reg.* 40,695-6 (1975).[15] For example, in 1983, based largely on advice from ABRA and other blood industry organizations, FDA promulgated donor screening recommendations to prevent persons at high risk to AIDS from donating blood or plasma. These were recently updated.[16] A plasma center ignores these informal regulations at its peril.

In addition, a plasma center cannot be licensed without FDA approving its standard operating procedures manual ("SOP"). 21 C.F.R. Part 606. The SOP contains detailed information describing the procedures to which the center will adhere in all aspects of its operations, including donor suitability processing. These SOPs are lengthy, running several hundreds of pages, and complex. A center can be held in violation of law during an inspection if procedures specified in the SOP are not being followed.[17] Although the

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[15] See also Allera, "FDA's Use of Guidelines, Notices of Proposed Rulemaking and Compliance Policies as De Facto Rules: An Abuse of Discretion, 3 *Plasma Quarterly* 76, 77, 89 (September 1981).

[16] Guidelines published from 1973 to the present, including the donor screening recommendations referred to, are lodged with the Clerk of this Court.

[17] There are probably about 100 different SOP's which have been approved by FDA in the licensure process, as well as a standard SOP prepared by ABRA (a copy of which is lodged with the Clerk of this Court). See 21 C.F.R. § 606; letter from FDA to ABRA lodged with the Clerk of this Court.

Solicitor General argues that "Congress did not intend to regulate wholly-intrastate activities," and therefore there is no intent to bar local governments from legislating in the plasmapheresis field (U.S. Br. pp. 16-17 and n.15), the United States elsewhere recognizes that plasmapheresis "is performed on a local basis," *Id.* at 17, n.16. Indeed, numerous portions of the SOPs approved by FDA relate primarily or solely to local activities, and the regulations themselves affect "wholly-intrastate" activities, *see* 39 *Fed. Reg.* 18,615 (1974). FDA in practice has not agreed that Congress did not intend to regulate intrastate activities.

B. The National Blood Policy's Requirement of "Uniformity," Which the Eleventh Circuit Found to Control Decision in This Case, Is Compelled by the Nature of the Industry and Federal Goals Relating Thereto

1. FDA's regulations and regulatory activities are consistent with FDA exercising a uniform, national exclusive jurisdiction and with the Court of Appeals conclusion that the "goal of uniformity runs throughout the regulations." J.A. 58. That this should be so follows logically from the very nature of the conflicting interests inherent in attempting to meet the National Blood Policy requirement that there be enough product to meet demand safely. On one hand, if there were no donor suitability standards, undoubtedly there would be more than enough plasma to meet demand but some of it would be from unhealthy donors or donors whose health would be threatened by intensive plasmapheresis. On the other hand, if plasma were required to be totally disease-free, the number of donors would be limited and there would be a dramatic shortage of plasma. Only a single agency charged with the responsibility to "insure the availability of good quality plasma," 39 *Fed. Reg.* 18,615 (1974), can undertake the balancing of interests required to *both* protect donor health and assure the availability of good quality plasma.[18] Clearly, Hillsborough County cannot do so.[19] By its own admission, it has no interest in doing so. Its only interest is in the health of its residents. (County Br. p. 10.) And this interest runs directly counter to the national interest in assuring an adequate supply of plasma. If every local jurisdiction were permitted to impose restrictions on plasmapheresis under the guise of exercising its police power, the national policy of assuring an adequate, safe supply of plasma products will be frustrated and the health care system will not have access to the plasma based products it needs.

Plasma products are not like cosmetics. Their users generally cannot consider price or select alternate products. Several years ago, for example, an industry leader estimated the annual cost for moderate to severe hemophiliacs to acquire AHF concentrate, and thus avoid crippling joint bleeds and pain relief not available from other therapies, at between $4,000 and $10,000 per year.[20] Any increase in cost wrought by local ordinances could have a disastrous effect on this group. Restrictions on paid plasmapheresis programs, in the opinion of a leading treater of hemophilia patients,[21]

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[18] The balancing is reflected in comments by Dr. John Petricciani, present Director, Division of Blood and Blood Products, FDA, to a forum on plasmapheresis: ". . . the basic reason the Division even exists is to provide protection to the public. On the one hand the public isn't going to be protected if we take our responsibilities casually and are indiscriminately permissive in our regulatory activities . . . [o]n the other hand, I am just as firmly convinced that the public is not being well-served by inappropriate regulation . . . [t]he overall philosophy, then, is to try to balance those extremes, and to achieve a high level of protection for the public while not stifling research and product development." 7 *Plasma Quarterly* 126 (Winter 1985).

[19] The complexity of the scientific issues—to which the Federal regulations and FDA's guidelines are competent witness—suggest that the County would have to possess substantial scientific expertise to be able to do so.

[20] Randolph, "Plasma, Its Derivatives and Market," 1 *Plasma Quarterly* 74, 75 (September, 1979).

[21] Aledort, "The Availability of Plasma Products and the Care of Hemophilia Patients," 246 *J.A.M.A.* 157 (July 10, 1981). Aledort also points

> would be injurious to many patients in the United States and abroad. Restrictions would be particularly damaging to the United States hemophilia patients.

While not every action which would restrict plasma supply is inappropriate, the adverse impact of such actions should be weighed by an agency having the expertise and responsibility to do so.[22]

The need for uniformity, dictated by the National Blood Policy, is also supported by the fact that the plasma industry is generally not very profitable.[23] Testimony at trial showed that direct and indirect costs resulting from the County Scheme, coupled with an anticipated substantial decline in donors, would cause AML to operate at a loss.[24] If the County Scheme stands, other jurisdictions where

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out that American hemophiliacs pay substantially less per unit of activity than the hemophiliac patients abroad. This is partly explained by the extensive plasmapheresis activity—both paid and voluntary—in the U.S.

[22] There are compelling reasons, such as concerns about AIDS, to risk distorting plasma and whole blood supply, even if the cost of the products will increase. Screening procedures designed to eliminate from the donor pool persons at risk to AIDS have led to a decline in the donor pool at both plasma centers and whole blood facilities.

The AIDS crisis illustrates the dominance of the federal interest in blood products in another way. The AIDS epidemic has brought a dramatic change in the way the American people perceive the blood banking community. *See e.g.*, "AIDS and the Growing Blood Scare," *Washington Post*, p. B1 (June 18, 1983). Hemophiliacs are asking whether they should continue prophylactic care with AHF concentrate. States are asking whether they should be taking action to regulate blood banking and plasmapheresis or related activities. It is a certainty that no two communities will see the problem the same. While a variety of regulatory initiatives are possible, such local responses are not the answer to AIDS-related concerns because they will restrict the blood and plasma supply without solving the underlying problem.

[23] Drake *et al.*, *The American Blood Supply*, M.I.T. Press, 1982, at 136. *See also Drake*, Table 6.6. at 73.

[24] Trial Transcript (Tr.), pp. 49, 51-2, 54-5, 81-2; PX 20, 21.

people decide they do not want plasma centers, *see* Plaintiff's Exhibit 14 (proceedings before the County Council), may adopt restrictive ordinances, and many plasma centers may face the same burdens and possibly unprofitable operations.[25] The inevitable result must be a reduction in plasma supplies and a concomitant increase in the price of plasma products. These costs will become part of the spiraling rise in health care costs. OTA, *supra*, at 8, 17.

At trial, Appellee estimated the cost impact of the County's regulations as being more than about $7.00 per liter in additional costs, including an estimated decline in the donor population, but not including the additional cost of an independent physical examination and other donor registration costs.[26] Industry is aware of other cost push factors, of which Hillsborough County may not be aware and in any case has no responsibility to consider.[27] The

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[25] For example, Pima County, Arizona proposed similar local regulation of plasma centers, but withdrew its proposed ordinance when the Eleventh Circuit decision was published. A bill recently introduced in the Texas legislature would ban plasmapheresis of any person not holding a driver's license or a certificate issued by the Texas Department of Public Health. Texas HB No. 1102 (Feb. 22, 1985) (lodged with the Clerk of the Court). Other jurisdictions have tried to regulate plasmapheresis, or ban the purchase of blood and plasma from donors, *see State of Wisconsin* v. *Interstate Blood Banking, Inc.*, 65 Wis.2d 482, 222 N.W.2d 912 (1974), and others have seriously restricted or banned plasma center operation through the application of zoning laws.

[26] *See* Tr. at 51. A physical examination comparable to that required by FDA could be $75.00 or more. At the present time, fractionators are paying approximately $55.00 for a liter of plasma and obtaining products with a total sales value of about $89.00. Thus, the fractionator has only $34.00 to cover manufacturing, marketing, all overhead, research and development, as well as profit and taxes. Any amount added to the raw material cost will ultimately be added to finished product prices.

[27] These include use of a test for the antibody to the virus thought to cause AIDS, increased manufacturing costs resulting from use of a heat treatment process developed to make coagulation products safer, and a dramatic rise in price of "recovered plasma," caused by short supply of source plasma. Recovered plasma, salvaged from whole blood toward the end of its shelf life, has less value as manufacturing raw material than source plasma.

combination of local regulation with these market forces and the requirements of FDA is obviously significant. As prices go up and plasma is harder to obtain, the burdens of local regulation become a more important factor in the conduct of business.[28]

The Government has conceded (U.S. Br. p. 8) that FDA "may some day decide to preempt such local regulations" if their "widespread adoption threatens to hamper" FDA's ability to assure the existence of an adequate supply of blood plasma. This implies that the nation would have to experience a shortage of plasma products before FDA would react to the patchwork of restrictive local regulation that could be so harmful to the nation's blood and plasma supply.[29] To wait until some user of plasma products, such as a hemophiliac, experiences the inability to buy the product because it is in short supply is irresponsible, contrary to the National Blood Policy, and contrary to the Commissioner's statutory duties.

The Commissioner's 1973 statement, then, is not dispositive of this case and long since has ceased being an accurate statement of FDA's position. In light of later developments, it should not even be accorded any weight in the legal determination to be made by this Court whether FDA's comprehensive scheme now preempts the County's limited, but conflicting rules.[30]

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[28] *See* OTA, supra, at 68; Grossman and Schmitt, "The Plasma Derivative Market: An Overview," prepared for the U.S. Congress Office of Technology Assessment, Contract No. 433-5650, p. 39.

[29] Just as product liability laws have caused manufacturers of certain vaccines to withdraw from the market (*See* "Product Liability: The New Morass," *New York Times*, Section 3, p. 1 (March 10, 1985)), local regulation can cause plasma centers to withdraw from the market. In 1972, at the time Dade County passed an ordinance similar to Hillsborough County ordinances, there were eleven plasma centers. Today there are two.

[30] As shown, FDA abandoned its 1973 position almost immediately after enunciating it. Because of this shift in regulatory positions, there is no reason to defer to the Commissioner's 1973 statement, for "[i]t is enough

C. The Eleventh Circuit Decision, Based on *Pennsylvania* v. *Nelson*, Correctly Found That the Local Scheme Is Preempted

The National Blood Policy's emphasis on uniformity and assuring an adequate supply of blood and blood products is no accident. Its architects recognized the relationship between regulatory uniformity and the need to balance competing policy goals to achieve both donor safety and an adequate supply. The County's regulations do not recognize that relationship and risk disrupting an industry that serves the vital needs of the American health care community.

Analysis begins with the two statutes on which FDA's regulations are based.[31] PHS Act Section 351 expresses Congress' intent that the federal regulation of biological products was a subject so imbued with the national interest that a strong scheme of federal regulation should be imposed. In pertinent part, Section 351 provides:

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to say that [the agency's positions] have not been uniform and do not establish any settled interpretation that is applicable here." *United States* v. *Missouri Pac. R.R.*, 278 U.S. 269, 282 (1929). Moreover, this Court ought not to accord deference to the position advanced here for the first time in this litigation by counsel for the United States that FDA's regulations do not preempt the County scheme. It is well-established that reviewing courts must accord deference only to positions actually relied upon by an administrative agency, and not those simply advanced by counsel in litigation. *E.g., American Textile Mfrs. Inst.* v. *Donovan*, 452 U.S. 490, 539 (1981); *SEC* v. *Chenery Corp.*, 318 U.S. 80, 94-95 (1943). In face of the National Blood Policy, upon which *amici's* members have relied, FDA's decision to abrogate the National Blood Policy's interest in uniformity by not preempting local regulations should, at a minimum, not be accorded substantial deference by the courts until it has been considered in a process which parallels that by which the National Blood Policy was developed, involving all the concerned parties, including Congress.

[31] Not contested in this case are three significant propositions: first, FDA's regulations are within its statutory authority. (U.S. Br. p. 7) Second, FDA has full authority to issue regulations which have a preemptive effect. (U.S. Br. p. 18) Third, these regulations are comprehensive. (County Br. p. 10)

> (a) *No person* shall *sell,* . . . any . . . blood, blood component, or derivative . . . *unless* (1) such . . . blood, blood component or derivative . . . *has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary.* . . .
>
> (d) *Licenses for* the maintenance of *establishments . . . may be issued only upon a showing that the establishment and the products . . . meet standards,* designed to insure the continued safety, purity and potency of such products, *prescribed in regulations, . . . All such licenses shall be issued, suspended, and revoked as prescribed by regulations.* . . .

42 U.S.C. § 262 (emphasis added). The statute's very restrictive terms permit the inference that Congress intended to comprehensively and completely regulate blood and derivatives and to bar any standards that differed from the Federal standards.[32] The so-called "new drug" section of the FDC Act, 21 U.S.C. § 355,[33] has the same structure as Section 351 and can be similarly interpreted. See also *National Women's Health Network, Inc.* v. *A.H. Robins Company, Inc.,* 545 F. Supp. 1177 (D. Mass. 1982) (FDC Act would preempt state law "recall theory"). But even if the statutes alone do not require preemption, FDA's comprehensive regulations clearly do.

Pennsylvania v. *Nelson,* 350 U.S. 497 (1955), requires that three questions be analyzed. First, is the regulatory scheme so comprehensive that it is reasonable to assume that Congress left no room for local supplementation? *Id.* at 502. Second, is the federal interest in the subject

[32] See *Armour and Company* v. *Ball,* 468 F.2d 76 (6th Cir. 1972). The statutory language considered in *Armour* was not unambiguously preemptive, as the law there at issue permitted state action "consistent" with the Federal law as to "matters regulated" under the Federal Act. Nonetheless, the Sixth Circuit concluded that all but identical state standards were preempted.

[33] Biological products are also drugs subject to provisions of FDC Act. *See, e.g.,* 37 *Fed. Reg.* 17,419 (1972).

matter so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject? *Id.* at 504. Third, does the local ordinance conflict with the federal regulation or will its enforcement frustrate national interests? *Id.* at 505. In this case, all three questions must be answered "yes."

1. That FDA's regulations are comprehensive is conceded by the Solicitor General (U.S. Br. p. 7) and by the County. County Br. p. 10. Federal regulations cover every aspect of plasmapheresis, including donor safety.[34] Each of the purported "additional protections" provided by the County scheme[35] is, in fact, nothing more than a different technique for dealing with a concern already addressed by FDA. "Vendor registration," for example, is an attempt to prevent overbleeding but the Commissioner was aware of the problem and addressed it adequately. That the County disagrees with a means chosen by the federal agency having expertise does not demonstrate that the federal regulations do not preempt local action on the same subject matter.

This is especially so where the available evidence suggests that the means required by the Federal regulations does accomplish the intended purposes. As shown in a study of 6,271 first time donors during the period between January 1, 1978 and March 1, 1978 and a total of 30,214 donations by these donors, there were 1,813 rejections or deferrals resulting from: lab tests and the donor screening process (59.7%), donor history (25.1%), and the balance

[34] If the regulations themselves are not "comprehensive," the guidelines and interpretations and the approved center SOP fill the gaps.

[35] The United States, the local government *amici* and the County characterize FDA's regulations as "minimum" standards. There is no authority for that characterization in the *Federal Register* preambles or in the regulations themselves. To the contrary, the Commissioner describes the standards as "uniform", 39 *Fed. Reg.* 26,161, 26,162 (1974), "comprehensive", *ibid.*, "specific", 37 *Fed. Reg.* 17,419, 17,420 (1972), designed to assure "high quality throughout the nation," 39 *Fed. Reg.* 26,165 (1974).

from donor behavior. Approximately 97 rejections resulted from the donor being observed to be under the influence of alcohol and 18 because of needlemarks. 278 rejections were based on the donor returning too soon following a previous plasmapheresis. Significantly, 41 donors were rejected because of suspected "cross-donating," or giving plasma at another center.[36]

The County's assertion that FDA regulations do not protect against multi-center over-bleeding demonstrates the County's lack of understanding of the very Federal regulations which it claims the right to enforce. The regulations require that each potential donor be asked about his last plasmapheresis session and that the answer be recorded, that the phlebotomist examine both arms for evidence of venipuncture (also useful in screening out intravenous drug users), and that the donor's hematocrit and total protein be tested and recorded. 21 C.F.R. 640.63. These tests will indicate whether the donor has subjected himself to overbleeding. 38 *Fed. Reg.* 19,364 (1973).

Each of the other "additional protections" found in the County scheme are of the same character: a subject covered by FDA but not to the satisfaction of the County.[37] The

[36] Reasor, "Rejection and Attrition of Compensated Plasmapheresis Donors," 1 *Plasma Quarterly* 72, 71-88 (Sept. 1979) (hereinafter cited as "Reasor"). There was no evidence presented at trial that the Federal regulations are not adequate to prevent cross-donating. Indeed, at trial, there was no evidence of *actual* instances of "cross-donating," only suspicions that this might be a problem. See Tr. 63.

[37] The Federal provision on physician examinations is 21 C.F.R. § 640.63 (b); on alcohol breath-analysis, 21 C.F.R. § 640.69(d); on inspection, 21 C.F.R. § 640.69(c); and on record keeping, 21 C.F.R. § 640.72.

The County justifies its requirement on breath-analysis by claiming it will assure that the donor gives "truly informed consent" and by referring to newspaper reports of a hemolytic reaction incident. (County Br. p. 18 n.21). The first of the articles cited shows that there was a mixup by center workers, not a problem with an uninformed or intoxicated donor. Informed consent, re-infusion procedures, and hemolytic reactions are all described in the Federal regulations and in approved SOPs including

County attempts to evade this truth by arguing that the dominant federal interest is to "insure a safe and plentiful product in interstate commerce" (County Br. p. 10 n.13), not in donor safety. This contention is simply unfounded in face of the Commissioner's statements that, for example, he was including "specific provisions designed to protect the health and well-being of the donor," 37 *Fed. Reg.* 17,419, 17,420 (1972), and protection of plasma donors was "one of the major purposes of the regulations." 41 *Fed. Reg.* 10,762-3 (1976).[38]

2. The Commissioner himself recognized that the National Blood Policy was "comprehensive" and that one of the "methods . . . to implement the policy" was employment of "the full regulatory authorities now vested in the federal government . . . for the purpose of assuring uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation." 39 *Fed. Reg.* 32,703 (1974) (quoting from 39 *Fed. Reg.* 9,329-30). The statements of the National Blood Policy itself are not equivocal on the importance of the federal interest.[39]

Congress periodically reviews the status of the National Blood Policy. In 1979, then Senator Schweiker held hear-

ABRA's Industry Manual. It is unfortunate but not surprising that an industry that performs 10,000,000 procedures annually has mistakes on rare occasions. The County requirement that donors be free of hepatitis largely duplicates FDA's regulations, which require that every unit must be tested, positive units be destroyed and positive donors be rejected. 21 C.F.R. §§ 640.63 (c)(11), 640.67.

[38] It is significant that the County's scheme does not address the two issues that give rise to "the greatest controversy" regarding donor safety—limitations on the volume and frequency of donation. OTA, *supra*, at 40. The County's claim to have supplemented FDA's regulations is hollow indeed.

[39] This Court has held that the FDC Act should be given a liberal construction consistent with its overriding purpose to protect the public health. *U.S.* v. *An Article of Drug, . . . Bacto-Unidisc,* 394 U.S. 784, 798 (1960).

ings regarding the voluntary sector's progress toward the goals of the National Blood Policy. Hearing, June 7, 1979, before Subcommittee on Health & Scientific Research of Committee on Labor & Human Resources, U.S. Senate, G.P.O., 1979. In 1983, in response to concerns about the blood supply, Congressman Dingell asked the Office of Technology Assessment to study the entire field of blood and blood products for possible congressional action. OTA's study, recently released, concluded that the nation's blood supply, including the supply of plasma products, is safer than ever before. OTA, *supra* at 37. As the report reveals, Federal involvement in the blood field is far more extensive than just FDA's regulatory efforts and includes, for example, reimbursement through Medicare for blood and blood products. *See* OTA, *supra* at 41-48.

Thus, blood and plasma are not a subject matter like avocados, which this Court deemed "an inherently unlikely candidate for exclusive federal regulation." *Florida Lime and Avocado Growers, Inc.* v. *Paul,* 373 U.S. 132, 143 (1963).[40] Rather, plasma is a subject more like tamper-resistant packaging where FDA exercised authority under the FDC Act to preempt state regulation of packaging. FDA recognized that over the counter (OTC) drugs are part of national commerce, and that local requirements would interfere with Federal objectives and the distribution of OTC drugs. FDA also balanced the need for protection with the potential burdens and costs. *See* 47 *Fed. Reg.* 50,442, 50,443, 50,447-8 (1982).[41]

Moreover, the County is unable to point to any particular "local needs" (U.S. Br. p. 12) not addressed in the Federal

[40] *Florida Lime* was a case where "Congressional superintendence of the field" was "partial", 373 U.S. at 145, not "comprehensive" and total, as here.

[41] See also FDA's regulations on a warning to pregnant or nursing women on OTC drugs, recognizing the national interest in a uniform warning and the confusion that differing local requirements would engender. 47 *Fed. Reg.* 54,750, 54,756 (1982).

regulations, any circumstances that suggest the County is different from other jurisdictions as respects plasma donors, or any factor that suggests that its citizens need more protection than those recognized by FDA as needing protection, 39 *Fed. Reg.* 26,161 (1974), from "exploitation," *Id.* at 26,162. Characterizing the County's interest as being the strong "traditional interest [of a local government] in protecting the health of [its] citizens" (U.S. Br. p. 25) is not sufficient to prevent Federal law from acting exclusively to regulate such subject matter. *Fidelity Federal Savings & Loan Association* v. *De la Cuesta,* 458 U.S. 141 (1982).

3. As this Court said in *Michigan Canners & Freezers Association, Inc.* v. *Agricultural Marketing and Bargaining Board,* 104 S.Ct. 2518, 2523:

> even in the absence of express preemptive language, Congress may indicate an intent to occupy an entire field of regulation, in which case the State must leave all regulatory activity in that area to the Federal Government, e.g. *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta,* 458 U.S. 141, 153 (1982); *Rice* v. *Santa Fe Elevator Corp.,* 331 U.S. 218, 230 (1947). Finally, if Congress has not displaced state regulation entirely, it may nonetheless preempt state law to the extent that the law actually conflicts with federal law. Such a conflict arises when compliance with both state and federal law is impossible, *Florida Lime & Avocado Growers, Inc.* v. *Paul,* 373 U.S. 132, 142-143 (1963), or when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines* v. *Davidowitz,* 312 U.S. 52, 67 (1941). See also *Fidelity Federal S&L, supra,* at 153.

National policy recognizes two goals that are, as described above, competing: assuring an adequate supply of blood and blood products and protecting the donor. Because the reconciliation of these national goals requires a balancing, local regulation which differs from FDA's scheme and which serves only one of the goals, that of donor health,

will inevitably stand "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines* v. *Davidowitz*, 312 U.S. at 67, by both creating conflicts and frustrating the uniformity so essential to the "purposes and objectives of Congress."[42]

The Eleventh Circuit found that the County scheme "imposes burdensome and expensive requirements in addition to the requirements of the comprehensive federal scheme." J.A. 59. Plasma centers in the County now have two sets of rules to play by. For example, FDA's recent reduction of the frequency of mandatory inspections based on an establishment's compliance history, 48 *Fed. Reg.* 26,314 (1983), is effectively reversed by the County Scheme, even for a plasma center which has worked diligently to establish a record of high compliance. And it is possible that County inspectors, applying both Federal and County standards, will apply different standards in practice from Federal inspectors, creating compliance problems and conflicts.[43]

Daily reporting of *routine* information, an unusual requirement, is a very tangible burden of the County scheme. The information required to be forwarded daily to the

[42] There is some evidence that Hillsborough County (like other jurisdictions which have considered some form of regulation of plasmapheresis) was not concerned solely with the health of its residents. A perceived social problem of vagrancy and public inebriation is implicit in minutes of meetings of the County commissioners (see Plaintiff's Trial Exhibits 8 and 14), and correspondence of a County official showed his full awareness that the proposed regulation could put plasma centers out of business. (Plaintiff's Trial Exhibits 6 and 7). There is no suggestion, however, that Hillsborough County is willing to forego the availability of plasma products to treat, for example, its hemophilia patients or burn patients.

[43] As another example, under the provision permitting variances, 21 C.F.R. § 640.75, FDA guidelines now allow plasma centers to use "adequately trained physician substitutes" to perform some physician functions. The County scheme may not recognize this or other variances. See FDA Memorandum re "Physician Substitutes" (Dec. 14, 1984) lodged with the Clerk of this Court.

County (along with $1 per plasmapheresis session) is duplicated in records that must be kept until after the product expiration date. 21 C.F.R. § 606.160(d). Unless carefully monitored by persons equipped by training and experience to understand the data, these records are not meaningful on a daily basis. Rather, they take on significance in inspection and review of the records of a facility over a span of time, or for review in the case of an adverse reaction.[44]

In addition to these "burdensome and expensive" requirements, the County scheme contains other direct conflicts with the Federal regulations. Under Federal law, any person judged in good health and meeting certain specified test parameters is permitted to undergo plasmapheresis. By contrast, under the County scheme only persons who have been registered by the County can undergo plasmapheresis. The County system prohibits an otherwise eligible, healthy donor from being processed in accordance with Federal law and the center's SOP. Under the County scheme, the plasma center must turn that person away until he or she obtains a registration card. Obtaining the card will require time—perhaps a few days—and the expense of the physical examination, which may be given by doctors who are unfamiliar with plasmapheresis.

[44] There is also a direct conflict between FDA's regulations and the Ordinances concerning the sensitive issue of the confidentiality of personal health information provided by blood donors. Under FDA's regulations, donor health records are created and maintained by the collection facility itself, rather than by FDA, 21 C.F.R. § 600.12, and would not be subject to the federal disclosure provisions of the Freedom of Information Act, 5 U.S.C. Section 552a, or the exceptions to the Federal Privacy Act. *Forsham* v. *Harris*, 445 U.S. 169, 182 (1980). By contrast, the Ordinances specifically permit disclosure of the information submitted daily by the Health Department if "such disclosure is directly related to and necessary for enforcement of this Ordinance or as is required by law." Ordinance 80-12, § 6(E). This more permissive approach would undoubtedly have a chilling effect upon willingness of potential donors to donate plasma and to be candid in revealing details of their medical history.

Hepatitis plasma is but an example of the conflict created by the donor registration scheme.[45] There are numerous "disease" plasmas which can be drawn under Federal law if a license is obtained. Donors who are sources of "disease" plasma may have a short-term illness, and therefore, have an antigen, antibody or other protein substance of medical value for only a short time. If a plasma center cannot access such persons quickly, the desired protein may disappear. FDA recognized that many such persons can be safely plasmapheresed and has developed licensing procedures to accommodate these special needs. A local registration requirement and evaluation by physicians lacking experience is, however, likely to delay the plasmapheresis of these persons beyond the useful period for doing so.

The County scheme thus frustrates the implementation of national policy by standing "as an obstacle to congressional purpose and objectives." *Capital Cities Cable, Inc.* v. *Crisp*, 104 S.Ct. 2694 (1984). First, the goal of assuring a "continuous and healthy donor population" will be frustrated because the burdens imposed by the County's regulations will diminish the number of persons ready and willing to provide their plasma.[46] Second, the decline in donor population and the increased costs flowing from the County scheme will threaten the assurance of an adequate supply of plasma products. Third, the goal of uniformity in both the regulatory environment and in quality of plasma products will be frustrated in that there will be—inevitably—a patchwork of regulatory standards for plasmapheresis (and bloodbanking). Each of the major fractionators operates many centers. For them, a regulatory patchwork is not just an inconvenience; it poses operating, training, and quality control problems. Plasma—and blood—is too complex and too important to be subject to the regulatory thought processes of hundreds of municipal officials.

[45] The County's claim that this conflict is "illusory" is confusing. (County Br. p. 15). Persons whose plasma is useful for production of hepatitis vaccine are persons who have been exposed to hepatitis and whose plasma contains Hepatitis B antigen. These persons will test positive and will be unable to receive a donor card. Thus, the donor registration requirement will effectively prevent a center from collecting hepatitis plasma.

[46] There was proof at trial that the donor population at AML would decrease significantly as a result of the Ordinances. Though the District Court found it speculative, the Court of Appeals was not, apparently, troubled by that. J.A. 59. *Cf. Dixie Dairy Co.* v. *City of Chicago*, 538 F.2d 1303 (7th Cir. 1976) (speculative evidence may be a necessary part of proving the burdens that flow from dual regulation).

CONCLUSION

"Human blood is a priceless resource." 39 *Fed. Reg.* 18,614 (1974). The National Blood Policy and statements of FDA's Commissioner and of other representatives of the Federal Government testify to the importance national policy attaches to blood and blood products. This interest, which mandates uniformity in regulatory activities to accomplish the goal of assuring an adequate supply of safe blood and plasma derivatives, overrides the interests of local jurisdictions in regulating activities already thoroughly and adequately regulated by FDA. For these reasons, the Eleventh Circuit properly held the County scheme preempted by FDA's regulations. This Court should affirm that decision.

Respectfully submitted,

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APPENDIX

APPENDIX A

CODE OF ETHICS
of
American Blood Resources Association

Code of Ethics

IT SHALL BE THE HOPE, PROMISE, AND THE DUTY OF MEMBERS OF THE AMERICAN BLOOD RESOURCES ASSOCIATION

1. To INSURE an adequate and safe supply of blood and blood derivatives for medical, pharmaceutical, and scientific use.
2. To MAINTAIN the highest professional standards in their facilities.
3. To UTILIZE modern tested collection methods to insure maximum donor safety.
4. To INFORM the public of the need for and uses of blood and blood derivatives.
5. To ENCOURAGE the public to participate in blood derivative programs.
6. To FOSTER research and development in all areas of blood and blood derivative utilization.
7. To COOPERATE with all levels of government initiating programs affecting blood and blood derivative collection, utilization, and safety.
8. To PROMOTE and maintain cordial and unselfish relationships with members of their own profession and of other professions for the exchange of information concerning the utilization and preparation of blood and its products to the advantage of mankind.
9. To RECOGNIZE that the ultimate purpose of the membership is service to the patient.